

### **DETAILED ACTION**

1. Claims 1-15 are pending in this application.

#### ***Priority***

2. The examiner acknowledges this application is a continuation-in-part of Application No. 10/351,755, now Patent No. 7,255,105, filed on Jan. 27, 2003, which is a continuation-in-part of Application No. 09/688,229, now Patent No. 6,668,828 filed on Oct. 16, 2000.

#### ***Specification***

3. The disclosure is objected to because of the following informalities: Examiner request applicant update the following U.S. patent application to the appropriate patent number as these applications have been issued: U.S. Application No. 10/351,755, is now Patent No. 7,255,105 and U.S. Application No. 09/688,229, is now Patent No. 6,668,828. Appropriate correction is required on page 1 & 16 of the disclosure.
4. The abstract of the disclosure is objected to because it compares the instant invention to the prior art. Correction is required. See MPEP § 608.01(b).
5. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use

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thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of **the invention and should not compare the invention with the prior art.** (Bolding added for emphasis).

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

6. The disclosure is objected to because of the following informalities: on page 43, line 9, a space is missing between "Purge"steps".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 2, 10, 11, 14 & 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bathe et al., (5,558,083) in view of Bathe et al., (6,125,846).

Regarding claims 1-2, Bathe '083 discloses an apparatus with a front end (figure 1 starting with the N2 Supply (16) and going to flow sensor (26)) and a reservoir portion (figure 1 from (26) to (40)). See: figure 1.

Bathe '083 discloses a front end with a first solenoid purge valve (20) and reservoir solenoid valve (24), a first equalization valve (18) and a second equalization valves (14), a conduit (connecting the supply between 16 to the patient 42), a manifold (the junction where NO/N2 Supply and N2 Supply meet), a front end flow sensor (26), and a reservoir portion (figure 1 from (26) to (36)) which has a reservoir unit (28), a fluid manifold (where 54 meets 32), and a reservoir flow sensor. See: figure 1.

Bathe '083 further describes that a purge system is included that is activated to purge the various components and to fill the system with a gas. Bathe specifically teaches purging the front end of the system and then recharging the supply lines and then continuing to deliver gasses to the patient. Thus, by purging the front end and then recharging the system and continuing delivering gas to a patient, both the front end and the reservoir portion would be purged. See: col. 3, lines 10-13; col. 4, lines 24-39; col. 6, lines 16-20; and col. 8, lines 21-27.

Bathe '083 discloses all the limitations of claims 1 & 2, except that Bathe '083 uses flow sensors instead of pressure sensors as claimed.

Bathe '846 teaches that it is readily apparent that purge system sensors (40) can be flow sensors or pressure sensors that they are connected to a conduit to sense the flow or pressure and then relay that information to the controller (28). See: col. 4, lines 15-24.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system disclosed by Bathe '083 by substituting a pressure sensor for a flow sensor, as taught by Bathe '846 because of the

reasonable expectation either a pressure sensor or a flow sensor would work equally well as a purge system sensor.

Regarding claim 10, the system disclosed by Bathe '083 is for administering therapeutic gases patients which has a CPU that automatically controls the first and second solenoid valves. The system disclosed by bathe '083 has a high pressure regulator (17) and the reference teaches a method of purging the front end. However, Bathe '083 lacks a pressure sensor as claimed. See: col. 5, line 60 – col. 6, line 20.

Bathe '846 teaches that it is readily apparent that purge system sensors (40) can be flow sensors or pressure sensors that they are connected to a conduit to sense the flow or pressure and then relay that information to the controller (28). See: col. 4, lines 15-24.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system disclosed by Bathe '083 by substituting a pressure sensor for a flow sensor, as taught by Bathe '846 because of the reasonable expectation either a pressure sensor or a flow sensor would work equally well as a purge system sensor.

Regarding claim 11, the system disclosed by Bathe '083 is for administering therapeutic gas patients and Bathe '083 discloses a system with a reservoir portion (figure 1 from (26) to (36)) which has a reservoir unit (28), a plurality of fluid manifolds (where 54 meets 32 & 38 meets 36) and a reservoir flow sensor (46). See: abstract and figure 1.

As discussed above, by purging the front end and then recharging the system and continuing delivering gas to a patient, both the front end and the reservoir portion would be purged by the method of Bathe '083. However, Bathe '083 lacks a pressure sensor as claimed.

Bathe '846 teaches that it is readily apparent that purge system sensors (40) can be flow sensors or pressure sensors that they are connected to a conduit to sense the flow or pressure and then relay that information to the controller (28). See: col. 4, lines 15-24.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system disclosed by Bathe '083 by substituting a pressure sensor for a flow sensor, as taught by Bathe '846 because of the reasonable expectation either a pressure sensor or a flow sensor would work equally well as a purge system sensor.

Regarding claim 14, the system of Bathe '083 is for administering a therapeutic gas to a patient. The system disclosed by Bathe '083 as a source of therapeutic gas (16) which is pressurized and is connected to a conduit (See: figure 1) and the conduit is connected to the first manifold (via 18 where the junction where NO/N<sub>2</sub> Supply and N<sub>2</sub> Supply meet) and gas flows from the supply through the nitric oxide delivery system. Finally, Bathe '083 provides a method of purging the front end via purge valve 20. See: figure 1.

However, Bathe '083 does not specifically disclose permitting gas to flow between the source of therapeutic gas and a first fluid manifold when pressure of the

source of therapeutic gas is greater than the pressure of the first fluid manifold plus a first equalization pressure or when the pressure of the first fluid manifold is greater than the pressure of the source of therapeutic gas plus a second equalization pressure and preventing flow from the source of therapeutic gas to the first fluid manifold and preventing flow from the first fluid manifold to the source of therapeutic gas at all other pressures, as Bathe '083 utilizes flow sensors.

Bathe '846 teaches that it is readily apparent that purge system sensors (40) can be flow sensors or pressure sensors that they are connected to a conduit to sense the flow or pressure and then relay that information to the controller (28). See: col. 4, lines 15-24.

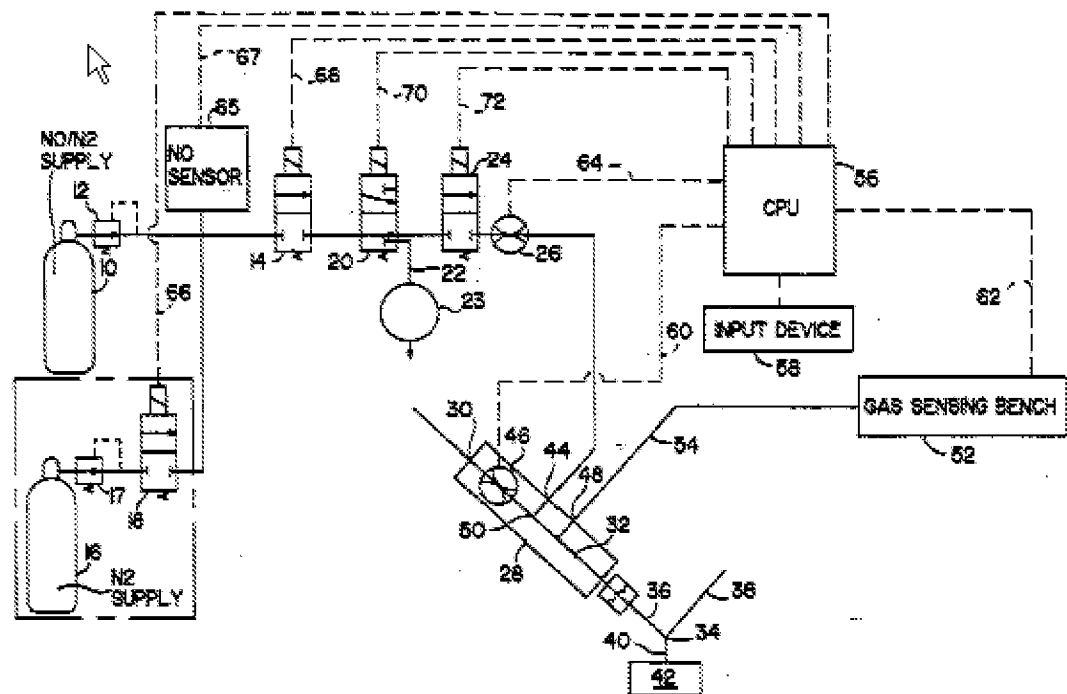
It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system disclosed by Bathe '083 by substituting a pressure sensor for a flow sensor, as taught by Bathe '846 because of the reasonable expectation either a pressure sensor or a flow sensor would work equally well as a purge system sensor.

Regarding claim 15, the system of Bathe '083 is for administering therapeutic gas to patients and Bathe '083 discloses a system with a front end with a solenoid purge valve (20) and reservoir solenoid valve (64) two equalization valves (18 & 14) a conduit (connecting the gas to the valves and then to the patient), a manifold (the junction where NO/N<sub>2</sub> Supply and N<sub>2</sub> Supply meet), a front end flow sensor and a reservoir portion with a reservoir unit (28), a fluid manifold (where 54 meets 32) a reservoir flow

sensor (46) a supply source (16) and Bathe '083 discloses purging the front end via purge valve (20). See: figure 1.

However, Bathe '083 lacks the front end and reservoir pressure sensors as claimed. Bathe '846 teaches that it is readily apparent that purge system sensors (40) can be flow sensors or pressure sensors that they are connected to a conduit to sense the flow or pressure and then relay that information to the controller (28)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system disclosed by Bathe '083 by substituting a pressure sensor for a flow sensor, as taught by Bathe '846 because of the reasonable expectation either a pressure sensor or a flow sensor would work equally well as a purge system sensor.



***Allowable Subject Matter***

9. Claims 3-9, 13 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claim 12 is allowed.

***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Stenzler (6,581,599); Sato et al., (4,681,099); Block, Jr., (5,394,881); Head et al., (6,142,147); Heinonen (6,474,333); and Bolam (2008/0006266) which are all drawn to gas delivery systems.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771